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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,706	09/08/2000	Randall B. Lauffer	MET/7 CON	3760

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 01/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/887,706

**Applicant(s)**

LAUFFER ET AL.

**Examiner**

Michael G. Hartley

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 64-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 64-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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***Response to Amendment***

The preliminary amendments filed 9/11/2000 and 7/16/2002 have been entered. The specification has been amended as requested, claims 1-63 have been canceled and new claims 64-83 have been added, which are the pending claims that have been examined herein.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 64-82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims fail to describe the SDTBM using reasonably generic terminology to convey that applicant had possession of such generic terminology as described in the specification. For example, the claims define the SDTBM to be a moiety that "comprises one or more alkyl, cycloalkyl, aryl or heterocyclic groups or combinations thereof" in claim 64. This definition would encompass almost any organic moiety and a vast and diverse group of biomolecules and small organics, including carbohydrates, polymers, large proteins, lipids, fatty acids, any known small organic heterocyclic compound, etc. The generic terminology used in the claims further complicates the vastly diverse possible chemical moieties, since the generic terminology in the claims does not describe the association between these moieties in combination, i.e., how are an alkyl and aryl structurally related, etc., or because of the open terminology "comprises" it is unclear as to what other moieties may be present, e.g., fluorinated alkyls, alkyl substituted dendrimers, buckyballs, etc. The specification clearly does not reasonably convey that any possible organic molecule can be attached to the chelate to provide the specific functionality set forth for the contrast agent in the claim (e.g., the R1 value and the percent binding). In fact, the specification only

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reasonably conveys the use of a limited number of specific small molecule groups as the SDTBM, as set forth on pages 39-42. This is a very specific class of small molecule organics, which does not show that applicant had possession of the vast and very diverse generic terminology used in the claims for the SDTBM, which would include various diverse biomolecules or almost any organic molecule. It is noted that while applicant has stated the use of some biomolecules as the SDTBM, applicant has not provided any description of specific biomolecules useful therefore and no examples have been provided therefore. The recitations in claims 71 and 72 also are not reasonable generic terminology because the specification does not describe the SDTBM to convey that applicant had possession of any organic moiety "comprising" various cycloalkyl groups or aryl groups, etc., wherein there is no structural relationship required, and any additional chemical moieties may additionally be present. For example, the recitation in claims 71 and 72 also encompasses biomolecules including proteins (i.e., proteins contain amino acids which "comprise" aryl groups), etc.

The dependent claims fall therewith

Note: the contrast agents set forth in claim 83 are described because these contrast have specific SDTBMs which are clearly described in the specification.

Further, in claim 82, the recitation of "phosphodiester, and amide moieties" as the linker was not described in the specification. The specification describes the linker on page 13 and include all of the chemical moieties in the claim, except for "phosphodiester, and amide moieties" as the linker, "L" as claimed in claim 82. This is a new matter rejection. This rejection (of claim 82 only) can be obviated by deleting these moieties from claim 82.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 64-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 64-82 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: The structural relationship between the various chemical moieties recited therein. The claims recite that the SDTBM "comprises" various organic moieties; however, this recitation omits any structural relationship to each other (e.g., when in combination thereof) or to other possible chemical moieties which are encompassed by the open terminology "comprising." It is improper to define a specific chemical compound, such as the SDTBM by only listing chemical moieties (or parts) which it comprises, since this fails to defined what else may be present and because structural relationships of chemical moieties to form compounds is so diverse. Further complicating the definition of the SDTMB is its differentiation to the chelate molecule. It is noted that a linker may not be present in the claimed contrast agents. Therefore, because of the open ended definition of the SDTMB and the chelate, as well as, their point of attachment, it is unclear when a substitution on a chelating agent (e.g., a methyl substitution on a chelate) would be only a substitution on the chelate and when it would constitute an SDTBM, as claimed, as there is no clear demarcation between the two, as defined by the instant claims.

The dependent claims fall therewith.

Note: inserting the specific contrast agents of claim 83 would obviate this rejection, since these chelates define an essential structural cooperative relationships of elements for the SDTMB.

### ***Specification***

The disclosure is objected to because of the following informalities: The specification include a figure on page 31, which is a graph. Figures, such as graphs, are not allowed in the specification.

Appropriate correction is required.

### ***Conclusion***

The claims are free of the art of record. While chelating agents having a structure encompassed by the instant claim language may be known, the prior art fails to teach or suggest the use of such

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contrast agents in methods of MRI and interventional therapy as claimed. The prior art fails to teach or suggest that such contrast agents would be specifically useful in a method of MRI and interventional therapy, as claimed because prior art fails to teach or suggest the specific imaging steps in combination with interventional therapy using contrast agents having the specific functional limitations set forth.

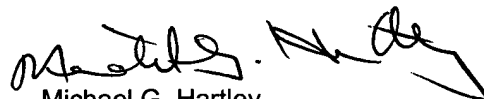
No claims are allowed at this time.

**Suggested allowable subject matter:** Limiting the claims to the contrast agents set forth in claim 83 to obviate the rejections under 35 USC 112 related to the SDTBM as set forth above and correcting following any other suggested to obviate rejections under 35 USC 112 mentioned above. However, it is suggested that the definition of the SDTBM is deleted from claim 64 to clarify the claim and that claims 71 and 72 are also canceled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
Michael G. Hartley  
Primary Examiner  
Art Unit 1616

MH  
January 14, 2003